K063202

Procurement Technology Systems, LLC

510(k) SUMMARY
ProDerma – Liquid Bandage

MAY - 2 2007

Submitted By:

Procurement Technology Systems, LLC
2375 Hwy 101 South, Bldg A
Greer, SC 29651
Telephone: 864-655-3500
Fax: 702-447-7243
Contact Name: Bill Griswold
Date Prepared: September 9, 2006

Device Name:

Trade Name: ProDerma
Common Name: Liquid Bandage
Product Code: KMF
Classification: Class I
CFR Section: 880.5090

Predicate Devices:

Liquiderm™ Liquid Adhesive Bandage – **K002338**
MFG By: Closure Medical Corporation
Marketed As: Johnson & Johnson Band-Aid® Liquid Bandage

LiquiShield™ Liquid Bandage – **K031321**
MFG By: Medlogic Global Ltd
Marketed As: LiquiShield™

DERMA+FLEX™ Gel Adhesive – **K050757**
MFG By: Chemence Medical Products
Marketed As: DERMA+FLEX™

Description:

ProDerma Liquid Bandage, a formulated Cyanoacrylate adhesive, is a violet tinted, clear liquid topical bandage composed of 2-Octyl and N-Butyl Cyanoacrylate monomers, a plasticizer and D&C violet #2 pigment.

ProDerma is packaged in a single use applicator containing up to 0.5 grams of product. The single use applicator is constructed in the shape of "tear drop" with the flat bottom side made of a flexible laminated film of Pet/AL/Nitrile and a flexible laminate of either Nitrile/PE or Nitrile/PP/PE formed as a blister on the top side with a polyurethane foam sponge for applying the liquid bandage. Each applicator is individually packaged in a blister with a Tyvek backing. The applicators are packaged in a box with a quantity ranging of 6 to 24 per box depending on the customer's requirements. The applicator is opened by folding over the packet

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at the narrow end under the foam sponge onto itself. The liquid flows into the foam sponge and is control by the user as pressure is applied to the applicator. ProDerma is then applied to the area in need.

Applicators sterilized to a Sterilization Acceptance Level (SAL) of 10^{-6} via commercially available irradiation facilities.

Indications for Use: ProDerma Liquid Bandage is indicated for Over-The-Counter (OTC) use to cover minor cuts, scrapes and minor irritations of the skin and help protect them from infection.

Contraindications: ProDerma should not be applied near the eyes. Do not use on areas that are infected or that show signs of infection or drainage. Avoid using ProDerma on major wounds that require wound closure with another device.

Technological Characteristics: ProDerma Liquid Bandage is applied to the desired area and polymerizes to form a mechanical bond with the skin. The polymerization process time varies based on the amount of ProDerma applied. The polymerization or set time typically occurs within less than 2 minutes. Once the polymerization is complete the resulting film acts as a cover allowing the wound to heal. During the healing process the polymer covering sloughs off naturally, as dead skin cells are shed and replaced with new ones.

Substantial Equivalence: ProDerma – Liquid Bandage is similar to the predicate devices listed in the section named "Predicate Devices" in that all are cyanoacrylate based liquid bandages. They are manufactured in a similar manner using synthesization and distillation methods and blending with other ingredients and sterilized in its finished package.

Testing Summary: ProDerma – Liquid Bandage has been subjected to the appropriate biocompatibility testing in accordance with ANSI/AAMI/ISO 10993 and the results have confirmed that the product is safe for its intended use. ProDerma has also been subject to the appropriate sterilization validation testing in accordance with ANSI/AAMI/ISO 11137 & 11737 and the results have confirmed that the method of sterilization selected for ProDerma provides a SAL level 10^{-6} in the finished individual applicator package.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Procurement Technology Systems, LLC
% Mr. Bill Griswold
P.O. Box 748
Duncan, South Carolina 29334-0748

MAY - 2 2007

Re: K063202
Trade/Device Name: ProDerma – Liquid Bandage
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: March 20, 2007
Received: March 21, 2007

Dear Mr. Griswold:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for PDoP

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063202

Device Name: ProDerma – Liquid Bandage

Indications for Use:

ProDerma Liquid Bandage is indicated for over-the-counter (OTC) use to cover minor cuts, scrapes and minor irritations of the skin and help protect them from infection.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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